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Patentanmeldung Nr. Patent application No. Demande de brevet n°

04016057.4

Der Präsident des Europäischen Patentamts;
Im Auftrag

For the President of the European Patent Office

Le Président de l'Office européen des brevets
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Method the for preparation of cosmetic emulsions

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METHOD FOR THE PREPARATION OF COSMETIC EMULSIONS

FIELD OF THE INVENTION

This invention relates to a method for the preparation of oil-in-water emulsions suitable
5 for cosmetic or topical dermatological products.

BACKGROUND OF THE INVENTION

Oil-in-water (O/W) emulsions typically contain between 5 and 40% by weight of oil
and/or oil soluble (hydrophobic) ingredients and between 60 and 95% by weight of water
10 and/or water soluble (hydrophilic) ingredients.

O/W emulsions are normally prepared by combining the oil phase and the water phase
together at high temperature (80–85 °C) and with vigorous agitation in the presence of an
emulsifier until the oil droplets are completely dispersed within the water. The emulsifying
agent is generally part of the oil phase, and is present at a level of between 10 and 30% by
15 weight of the total oil phase. The resulting emulsion must then be continuously agitated during
the cooling process in order to prevent separation (of the emulsion) into the original two phases.
Typically agitation is required until the emulsion has cooled to a temperature of 40 °C or below.
The process of heating the oil and water phases in order to achieve the emulsion is very time
and energy consuming as is the cooling down phase. Moreover, in products for topical
20 application the presence of the emulsifier in the finished emulsion presents a number of
drawbacks:

- 1) The presence of the emulsifier reduces the water repellency of the formulation once it
has been applied to the skin. This is particularly important for sunscreen applications
and color cosmetics.
- 25 2) In skin care products, the presence of the emulsifier increases the irritancy potential of
the formulation, in that it has a delipidizing effect on the skin.

Vegetable oil microspheres are discrete spheres which occur naturally in the seeds of
oilseed crops. They consist of an outer coat of proteins and an internal liquid, semi-solid, or low
30 melting solid collection of the triglycerides associated with the individual plant seed. For
example, safflower oil microspheres would contain the triglycerides with the fatty acid content
normally associated with that plant seed, i.e., 6.5% palmitic, 2.5% stearic, 11.5% oleic, 79%
linoleic, and 0.5% linolenic acids. Size and properties of these microspheres are dependent on

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the seed type, but for safflower seeds the microspheres are typically 3 μm in diameter and can be obtained as a 70% dispersion in water.

The preparation and several applications of oil bodies are described in a number of patents assigned to the Canadian company Sembiosys Genetics Inc., e.g. U.S. Patent No. 5 6,146,645. Three of these patents are discussed in the following.

Deckers et al., U.S. Patent No. 6,183,762, disclose the preparation of cosmetic compositions for various applications. However, in each one of the applications described, the oil and water phases of the emulsion are heated to temperatures of 70 °C or higher whereupon they are added together with agitation. After the emulsion has been prepared and cooling has 10 taken place (to 40 °C or lower) then the oil body (microsphere) emulsion is added.

In U.S. Patent No. 6,582,710, the same inventors claim the use of vegetable oil microspheres in cosmetic applications. Again all of the formulations are prepared in the traditional way, i.e. through the process of heating the oil and water phases independently, combining them together with agitation, and then cooling to 40 °C before addition of the 15 microspheres.

Another patent by the same inventors, U.S. Patent No. 6,599,513, describes the use of oil bodies to achieve finished formulations applicable to cosmetics. Again all of the Examples comprise a heating step.

20 SUMMARY OF THE INVENTION

We have found that we can prepare stable, cosmetically acceptable emulsions simply by adding the requisite water or oil soluble ingredients directly to the dispersion of washed oil bodies with stirring. No lengthy heating period is required and obviously no cooling period is needed either. The advantages of such an approach in terms of energy savings, preparation 25 time, and in increased product throughput should be obvious.

DETAILED DESCRIPTION OF THE INVENTION

As hereinbefore mentioned, the cosmetic or topical dermatological emulsions of the present invention are prepared by adding water and the cosmetically or dermatologically active 30 ingredients to a dispersion of washed oil bodies under stirring without heating, at a temperature of not more than about 40 °C. The order of addition is not critical and the ingredients may be added one at a time or in premixed form, e.g. water-soluble components as aqueous solution or mutually miscible liquid ingredients as a mixture. Additional oil soluble ingredients (e.g. UV

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chromophores, vitamins, etc.) can also be added to the dispersion of oil bodies. The stirring can be effected by essentially any sort of stirrer or impeller operated at appropriate speed.

The cosmetic or topical dermatological products that can be prepared by the method of the present invention are essentially all products comprising oil-in-water emulsions in lotion, cream or paste form, including, but not limited to, moisturizing preparations, ointments, skin reparatives, sunscreens, skin lighteners, and decorative cosmetics such as color foundation creams, eye shadow creams and tanner creams.

Preferably, the emulsion is a cosmetic product selected from the group consisting of moisturizers, ointments, cleansers, makeup removers, toners, night treatments, skin reparatives, sunscreens, skin lighteners, color foundations, eye shadows and tanners.

In one preferred embodiment, the product is a lotion.

In another preferred embodiment, the product is a cream.

The vegetable oil bodies can be obtained from any plant cells, including cells from pollens, spores, seeds and vegetative plant organs in which oil bodies or oil body-like organelles are present. Preferably, the vegetable oil bodies are obtained from plant seeds or fruits, more preferably from the group of plant species consisting of rapeseed, soybean, sunflower, oil palm, cottonseed, peanut, walnut, coconut, castor, safflower, mustard, coriander, squash, linseed, brazil nut, jojoba, avocado and maize. Most preferably, the vegetable oil bodies are obtained from safflower seeds.

The preparation of the vegetable oil bodies is disclosed in several patents, for example, U.S. Pat. No. 6,146,645. The preparation process comprises at least one washing step to accomplish removal of contaminating seed material, which is essential for obtaining a dispersion having properties suitable for being used in cosmetics. Furthermore, said removal of contaminating material reduces the risk of allergic reactions when the cosmetic preparation is applied to the skin.

The method of the present invention requires no additional emollients, emulsifiers etc. which constitutes a substantial advantage over the methods and products of prior art. In a preferred embodiment, no additional emulsifier is used.

The following non-limiting examples are illustrative of the present invention:

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EXAMPLES

General procedure:

All preparations have been carried out using a 2 L beaker and a Heidolph® RZR50 stirrer equipped with an anchor-type impeller of 10 cm diameter. The stirring speed is given in 5 min^{-1} ($1 \text{ min}^{-1} = 1 \text{ revolution per minute} \approx 1 \text{ rpm}$). The batch size was 1 kg in each example.

Materials:

All materials used in the examples are commercially available, in particular:

Stearic acid, octyl methoxycinnamate, paraffin oil, cetyl alcohol, urea, vitamin A, 10 vitamin E, glycerol, arbutin, polysorbate 80 and hydroxyethylcellulose are standard chemicals obtainable from several suppliers. Decaglycerol L DE, L-carnitine, Geogard® 361, Lonzeest® 143S (myristyl propionate), sorbitan monooleate and Aldo® MCT (medium chain triglycerides) are supplied by Lonza Inc., Fair Lawn, NJ. Novemer® EC-1 is available from Noveon Inc., Cleveland, OH. Almond fragrance 901A79 is available from Flavor & Fragrance Specialties 15 Inc., Mahwah, NJ. Safflower oil microspheres are available from Sembiosys Genetics Inc., Calgary, Canada. Kelzan®-T is available from CP Kelco, Wilmington, DE. The pigments used in examples 8 to 13, i.e., green color pigment, red cosmetic iron oxide, brown iron oxide and titanium dioxide are supplied by Whittaker, Clark & Daniels Inc., South Plainfield, NJ. Papain is available from Enzybel S.A., Villers-le-Bouillet, Belgium and bromelain from Marcor 20 Development Corp., Carlstadt, NJ. *Rumex occidentalis* extract is obtainable from Atrium Biotechnologies Inc., Fairfield, NJ.

An example of a typical sunscreen formulation prepared in the traditional way is shown below in Comparative Example 1. The process for preparation of a similar sunscreen via a 25 "cold process" approach is shown in Example 1. Examples 2 to 13 relate to various cosmetic formulations.

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Comparative Example 1**Sunscreen (SPF 13)**

Ingredients	% Weight
Stearic Acid	6.00
Octyl Methoxycinnamate	8.00
Paraffin Oil	3.00
Cetyl Alcohol	2.00
Myristyl Propionate (Lon zest® 143S)	3.00
Medium Chain Triglycerides (Aldo® MCT)	3.00
Sorbitan Monooleate	5.05
Polysorbate 80	3.95
Water	65.60
Geogard® 361 (Preservative)	0.40
Novemer® EC-1	1.00
Almond Fragrance # 901A79	q.s.

SPF = sun protection factor, q.s. = quantum sufficit

5 Procedure

Stearic acid, octyl methoxycinnamate, paraffin oil, cetyl alcohol, myristyl propionate, medium chain triglycerides, sorbitan monooleate and polysorbate 80 are mixed (phase 1) and heated to 80–85 °C with stirring to avoid charring and overheating. Water (phase 2) is heated to 80–85 °C. Phase 1 is added to phase 2 with vigorous stirring over a 30 minute time period. The temperature is maintained at 80 °C for an additional 30 minutes while agitation continues. The emulsion is then cooled while stirring vigorously until a temperature of 40 °C or less is achieved, whereupon the preservative, Novemer® and the fragrance is added. Total process time is approximately 4.5 hours.

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Example 1**Sumscreen (SPF ~15)**

Ingredients	% Weight
Octyl Methoxycinnamate	8.00
Water	76.60
Safflower Oil Microspheres (70%)	8.00
Decaglycerol L DE	5.00
Novemer® EC-1	2.00
Geogard® 361 (Preservative)	0.40
Almond Fragrance # 901A79	q.s.

Procedure

5 Add the water to the safflower oil microspheres and mix at 90 min^{-1} for 10 minutes. Add the decaglycerol to the mixture with stirring for 2 minutes at 85 min^{-1} . Add the methoxycinnamate and the preservative to the mixture and stir at 80 min^{-1} for 8 minutes. Add the Novemer® EC-1 and stir at 70 min^{-1} until the mixture begins to thicken and then increase the stirrer speed to $100\text{--}110\text{ min}^{-1}$ and stir for an additional 3 minutes. Total preparation time is ~23 minutes,

10 viscosity 10,240 mPa·s The formulation passed stability testing at 45 °C for two months.

Thus the formulation of Example 1 in which safflower microspheres were substituted for the diluents, emollients and emulsifiers that were used in the Comparative Example 1 was prepared with no heating, no cooling, in much less time, and with far fewer ingredients.

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Example 2Emulsifier Free Sunscreen

Ingredients	% Weight
Octyl Methoxycinnamate	8.00
Water	76.60
Safflower Oil Microspheres (70%)	8.00
Decaglycerol L DE	5.00
Hydroxyethylcellulose	2.00
Geogard® 361 (Preservative)	0.40
Almond Fragrance # 901A79	q.s.

Procedure

5 Add the water to the Safflower microspheres and mix at 90 min^{-1} for 5 minutes. Add the decaglycerol to the mixture with stirring for 2 minutes at 85 min^{-1} . Add the methoxycinnamate and the preservative to the mixture and stir at 80 min^{-1} for 8 minutes. Add Natrosol® (presolubilized) and stir at 90 min^{-1} until the mixture begins to thicken and then increase the stirrer speed to $100\text{--}110\text{ min}^{-1}$ and stir for an additional 15 minutes. Total preparation time is

10 ~30 minutes, viscosity $22,800\text{ mPa}\cdot\text{s}$. The formulation passed stability testing at $40\text{ }^{\circ}\text{C}$ for two months.

Many other cosmetic or topical dermatological products can be prepared in stable form via the cold process route, for example reparative creams/lotions, moisturizing creams/lotions,

15 lightener creams, ointment creams, exfoliating creams, eye shadow creams, color foundation creams or tanner creams (Examples 3–13).

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Example 3Reparative Cream

Ingredients	% Weight
Octyl Methoxycinnamate	8.00
Water	78.60
Safflower Oil Microspheres (70%)	7.00
L-Carnitine	1.00
Decaglycerol L DE	3.00
Novemer® EC-1	2.00
Geogard® 361 (Preservative)	0.40
Almond Fragrance # 901A79	q.s.

Procedure

5 Add the water to the safflower oil microspheres along with the L-carnitine and mix at 90 min^{-1} for 10 minutes. Add the decaglycerol to the mixture with stirring for 2 minutes at 85 min^{-1} . Add the methoxycinnamate and the preservative to the mixture and stir at 80 min^{-1} for 8 minutes. Add the Novemer® EC-1 and stir at 70 min^{-1} until the mixture begins to thicken and then increase the stirrer speed to $100\text{--}110\text{ min}^{-1}$ and stir for an additional 3 minutes. Total

10 preparation time is ~23 minutes, viscosity $17,800\text{ mPa}\cdot\text{s}$. The formulation passed stability testing at $45\text{ }^{\circ}\text{C}$ for two months.

Example 4Moisturizing Cream

Ingredients	% Weight
Octyl Methoxycinnamate	8.00
Water	69.60
Safflower Oil Microspheres (70%)	10.00
Urea	5.00
Decaglycerol L DE	5.00
Novemer® EC-1	2.00
Geogard® 361 (Preservative)	0.40
Almond Fragrance # 901A79	q.s.

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Procedure

Add the water to the safflower oil microspheres with urea and mix at 90 min^{-1} for 10 minutes.

Add the decaglycerol to the mixture with stirring for 2 minutes at 85 min^{-1} . Add the methoxy-cinnamate and the preservative to the mixture and stir at 80 min^{-1} for 8 minutes. Add the

5 Novemer[®] EC-1 and stir at 70 min^{-1} until the mixture begins to thicken and then increase the stirrer speed to $100\text{--}110\text{ min}^{-1}$ and stir for an additional 3 minutes. Total preparation time is ~23 minutes, viscosity 17,800 mPa·s. The formulation passed stability testing at 45 °C for two months.

10

Example 5Lightener Cream

Ingredients	% Weight
Water	84.00
Safflower Oil Microspheres (70%)	7.00
Arbutin	1.00
Decaglycerol L DE	5.00
Novemer [®] EC-1	2.00
Geogard [®] 361 (Preservative)	0.40
Almond Fragrance # 901A79	q.s.

Procedure

Add the water to the safflower oil microspheres with arbutin and mix at 90 min^{-1} for

15 10 minutes. Add the decaglycerol to the mixture with stirring for 2 minutes at 85 min^{-1} . Add the preservative to the mixture and stir at 80 min^{-1} for 8 minutes. Add the Novemer[®] EC-1 and stir at 70 min^{-1} until the mixture begins to thicken and then increase the stirrer speed to $100\text{--}110\text{ min}^{-1}$ and stir for an additional 3 minutes. Total preparation time is ~23 minutes, viscosity 13,220 mPa·s. The formulation passed stability testing at 45 °C for two months.

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Example 6Ointment Cream with Vitamin A and E

Ingredients	% Weight
Water	84.00
Safflower Oil Microspheres (70%)	10.00
Vitamin A	0.5
Vitamin E	0.5
Decaglycerol L DE	5.00
Novemer® EC-1	2.00
Geogard® 361 (Preservative)	0.40
Almond Fragrance # 901A79	q.s.

Procedure

5 Add the water to the safflower oil microspheres with vitamin A and E and mix at 90 min^{-1} for 10 minutes. Add the decaglycerol to the mixture with stirring for 2 minutes at 85 min^{-1} . Add the preservative to the mixture and stir at 80 min^{-1} for 8 minutes. Add the Novemer® EC-1 and stir at 70 min^{-1} until the mixture begins to thicken and then increase the stirrer speed to $100\text{--}110\text{ min}^{-1}$ and stir for an additional 3 minutes. Total preparation time is ~23 minutes,

10 viscosity 12,320 mPa·s. The formulation passed stability testing at 45 °C for two months.

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Example 7Botanical Exfoliating Cream

Ingredients	% Weight
Water	72.60
Safflower Oil Microspheres (70%)	10.00
Enzyme concentrate ¹⁾	2.00
Decaglycerol L DE	5.00
Novemer® EC-1	2.00
Geogard® 361 (Preservative)	0.40
Octyl Methoxycinnamate	8.00
Almond Fragrance # 901A79	q.s.

¹⁾ 18.9 mg papain (62000 PU) + 4.5 mg bromelain (3300 GDU) per 2 g solution (solvent: 50/50 mixture of decaglycerol and water)

5

Procedure

Add the water to the safflower oil microspheres with papain and bromelain and mix at 90 min⁻¹ for 10 minutes. Add the decaglycerol to the mixture with stirring for 2 minutes at 85 min⁻¹. Add the methoxycinnamate and the preservative to the mixture and stir at 80 min⁻¹ for 8 minutes.

10 Add the Novemer® EC-1 and stir at 70 min⁻¹ until the mixture begins to thicken and then increase the stirrer speed to 100–110 min⁻¹ and stir for an additional 3 minutes. Total preparation time is ~23 minutes, viscosity 17,310 mPa·s. The formulation passed stability testing at 45 °C for two months.

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Example 8.Eye Shadow Cream

Ingredients	% Weight
Water	80.30
Safflower Oil Microspheres (70%)	12.00
Green Color Pigment A2-2502	0.30
Decaglycerol L DE	5.00
Novemer® EC-1	2.00
Geogard® 361 (Preservative)	0.40
Almond Fragrance # 901A79	q.s.

Procedure

5 Add the water to the safflower oil microspheres with green color pigment and mix at 90 min^{-1} for 10 minutes. Add the decaglycerol to the mixture with stirring for 2 minutes at 85 min^{-1} . Add the preservative to the mixture and stir at 80 min^{-1} for 8 minutes. Add the Novemer® EC-1 and stir at 70 min^{-1} until the mixture begins to thicken and then increase the stirrer speed to $100\text{--}110\text{ min}^{-1}$ and stir for an additional 3 minutes. Total preparation time is ~23 minutes,

10 viscosity 17,820 mPa·s. The formulation passed stability testing at 45 °C for two months.

Example 9Color Foundation Cream

Ingredients	% Weight
Water	80.10
Safflower Oil Microspheres (70%)	12.00
Red Cosmetic Iron Oxide	0.50
Decaglycerol L DE	5.00
Novemer® EC-1	2.00
Geogard® 361 (Preservative)	0.40
Almond Fragrance # 901A79	q.s.

Procedure

Add the water to the Safflower microspheres with red iron oxide color pigment and mix at 90 min^{-1} for 10 minutes. Add the decaglycerol to the mixture with stirring for 2 minutes at

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85 min⁻¹. Add the preservative to the mixture and stir at 80 min⁻¹ for 8 minutes. Add the Novemer® EC-1 and stir at 70 min⁻¹ until the mixture begins to thicken and then increase the stirrer speed to 100–110 min⁻¹ and stir for an additional 3 minutes. Total preparation time is ~23 minutes, viscosity 17,200 mPa·s. The formulation passed stability testing at 45 °C for two months.

5

Example 10

Color Foundation/Tanner Cream

Ingredients	% Weight
Water	80.10
Safflower Oil Microspheres (70%)	12.00
Brown Iron Oxide # E 172	0.50
Decaglycerol L DE	5.00
Novemer® EC-1	2.00
Geogard® 361 (Preservative)	0.40
Almond Fragrance # 901A79	q.s.

10 Procedure

Add the water to the safflower oil microspheres with brown iron oxide color pigment and mix at 90 min⁻¹ for 10 minutes. Add the decaglycerol to the mixture with stirring for 2 minutes at 85 min⁻¹. Add the preservative to the mixture and stir at 80 min⁻¹ rpm for 8 minutes. Add the Novemer® EC-1 and stir at 70 min⁻¹ until the mixture begins to thicken and then increase the stirrer speed to 100–110 min⁻¹ and stir for an additional 3 minutes. Total preparation time is ~23 minutes, viscosity 16,200 mPa·s. The formulation passed stability testing at 45 °C for two months.

15

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Example 11Color Blush/Eye Shadow Cream

Ingredients	% Weight
Water	82.35
Safflower Oil Microspheres (70%)	10.00
Red Cosmetic Iron Oxide	0.25
Decaglycerol L DE	5.00
Novemer® EC-1	2.00
Geogard® 361 (Preservative)	0.40
Almond Fragrance # 901A79	q.s.

Procedure

5 Add the water to the Safflower microspheres with red cosmetic iron oxide color pigment and mix at 90 min^{-1} for 10 minutes. Add the decaglycerol to the mixture with stirring for 2 minutes at 85 min^{-1} . Add the preservative to the mixture and stir at 80 min^{-1} for 8 minutes. Add the Novemer® EC-1 and stir at 70 min^{-1} until the mixture begins to thicken and then increase the stirrer speed to $100\text{--}110\text{ min}^{-1}$ and stir for an additional 3 minutes. Total preparation time is

10 ~23 minutes, viscosity 16,890 mPa·s. The formulation passed stability testing at 45 °C for two months.

Example 12Color Blush/Eye Shadow Cream

Ingredients	% Weight
Water	77.60
Safflower Oil Microspheres (70%)	10.00
Red Cosmetic Iron Oxide	0.25
Decaglycerol L DE	5.00
Novemer® EC-1	2.00
Geogard® 361 (Preservative)	0.40
Almond Fragrance # 901A79	q.s.

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Procedure

Add the water to the safflower oil microspheres with red cosmetic iron oxide color pigment and mix at 90 min^{-1} for 10 minutes. Add the decaglycerol to the mixture with stirring for 2 minutes at 85 min^{-1} . Add the preservative to the mixture and stir at 80 min^{-1} for 8 minutes. Add the Novemer® EC-1 and stir at 70 min^{-1} until the mixture begins to thicken and then increase the stirrer speed to $100\text{--}110\text{ min}^{-1}$ and stir for an additional 3 minutes. Total preparation time is ~23 minutes, viscosity 16,890 mPa·s. The formulation passed stability testing at $45\text{ }^{\circ}\text{C}$ for two months.

10

Example 13Emulsifier Free Lightener/Exfoliating Cream

Ingredients	% Weight
Water	77.60
Safflower Oil Microspheres (70%)	10.00
Urea	1.00
Glycerol	2.00
<i>Rumex occidentalis</i> Extract	1.00
Kelzan®-T	3.00
Titanium Dioxide (Whittaker, Clark & Daniels # 3328)	5.00
Geogard® 361 (Preservative)	0.40
Almond Fragrance # 901A79	q.s.

Procedure

Add the water to the safflower oil microspheres with urea and mix at 90 min^{-1} for 10 minutes.

15 Add the glycerol and titanium dioxide and *Rumex occidentalis* extract with stirring for 2 minutes at 85 min^{-1} . Add the preservative to the mixture and stir at 80 min^{-1} for 8 minutes. Add the Kelzan®-T and stir at 70 min^{-1} until the mixture begins to thicken and then increase the stirrer speed to $100\text{--}110\text{ min}^{-1}$ and stir for an additional 3 minutes. Total preparation time is ~23 minutes, viscosity 14,500 mPa·s. The formulation passed stability testing at $45\text{ }^{\circ}\text{C}$ for two months.

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We claim:

1. A method for preparing a cosmetic or topical dermatological product comprising an oil-in-water emulsion, the method comprising the step of mixing at least one cosmetically or dermatologically active ingredient with an aqueous emulsion of washed vegetable oil bodies (microspheres) at a temperature of not more than about 40 °C.
5
2. The method of claim 1, wherein the product is a cosmetic product selected from the group consisting of moisturizers, ointments, cleansers, makeup removers, toners, night treatments, skin reparatives, sunscreens, skin lighteners, color foundations, eye shadows and tanners.
10
3. The method of claim 1 or 2, wherein the product is a lotion.
4. The method of claim 1 or 2, wherein the product is a cream.
15
5. The method of any of claims 1 to 4, wherein the vegetable oil bodies are selected from the group consisting of oil bodies obtained from rapeseed, soybean, sunflower, oil palm, cottonseed, peanut, walnut, coconut, castor, safflower, mustard, coriander, squash, linseed, brazil nut, jojoba, avocado and maize.
20
6. The method of claim 5, wherein the vegetable oil bodies are obtained from safflower.
7. The method of any of claims 1 to 6, wherein no additional emulsifier is used.

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Abstract

A novel method is disclosed for the preparation of oil-in-water emulsions suitable for cosmetic or topical dermatological products. The method comprises the step of mixing at least one
5 cosmetically active ingredient with an aqueous emulsion of washed vegetable oil bodies (microspheres) at a temperature of not more than about 40 °C.

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